

## REMARKS

Claims 1-11 and 14-43 are pending. Reconsideration of the application is respectfully requested in view of the remarks herein.

The Examiner has rejected claims 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39 and 41-43 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,726,923 to Lyer, et al. (hereafter “Lyer”). The rejection is respectfully traversed.

To maintain a 35 U.S.C. §102(e) rejection, a single reference must teach each and every element of a claim. Lyer fails to do so.

Applicants’ independent claim 1 recites a device for creating an anastomosis between first and second blood vessels. The device comprises, *inter alia*, an extravascular body, first securing means and second securing means. The extravascular body comprises an outer surface and an inner surface. The inner surface forms an opening configured to contact a portion of the first vessel received therein. The first securing means, i.e. adhesive, secures at least an end of the first vessel to the opening. The second securing means secures a portion of the second vessel to a corresponding portion of the outer surface of the extravascular body such that a hole formed in the portion of the second vessel is in fluid communication with the first vessel.

Applicants’ independent claim 29 recites a method for creating an anastomosis between first and second blood vessels. The method comprises, *inter alia*, adhesively attaching a portion of the first vessel to an extravascular body. The extravascular body comprises an opening therethrough. The opening is configured to receive and contact the portion of the first vessel. The extravascular body further comprises an outer surface, at least a portion of which is configured to contact a portion of the second vessel. The method further comprises attaching the

portion of the second vessel to the corresponding portion of the outer surface of the body, and creating an anastomosis between the first and second vessels through the opening in the body.

Significantly, both claims 1 and 29 recite the features of a first securing means for adhesively securing at least an end of the first vessel to the opening, and a second securing means for securing a portion of the second vessel to a corresponding portion of the outer surface of the body such that a hole formed in the portion of the second vessel is in fluid communication with the end of the first vessel. All other claims depend directly or indirectly from claims 1 and 29.

Lyer discloses a prosthetic device adapted for extravascular drug delivery. The prosthetic device is employed to prevent or suppress the possible failure of vascular grafts caused by the proliferation and migration of smooth muscle cells resulting in intimal hyperplasia in the blood vessel or the adjacent graft orifice. Specifically, Lyer discloses a dual layered prosthetic device externally wrapped or placed around the outer surface of a blood vessel or a graft (see line 65, col. 10 to line 20 col. 11 of Lyer). The device comprises an inner layer and an outer layer. The inner layer is made of bioresorbable protein collagen impregnated or saturated with antiproliferative or antistenosis drugs. The antiproliferative or antistenosis drugs imbibed in the inner layer permeate or diffuse through the outer surface of the blood vessel once the prosthetic device is wrapped around the blood vessel and function to inhibit smooth muscle proliferation and migration. The outer layer is a reinforcement layer functioning to limit the drug diffusion to the surrounding tissue and skin. The inner layer is attached to the outer layer by means of sutures, adhesives, staples or chemical bonding.

Lyer further discloses a prosthetic device used in connection with an arterio-venous fistulae, as shown in Figs. 7 and 8. This device is wrapped around both an arterial

structure and a venous structure. However, Lyer does not teach or suggest that the device is secured around either of the vessel structures. Further, the vessel structures are inserted into two corresponding holes formed perpendicularly in the device, and thus neither of the vessel structure is secured to the outer surface of the device, which feature is especially advantageous under such circumstances to prohibit the wrapping of a blood vessel, for example, a coronary artery.

Thus, what Lyer discloses is a sleeve-like drug reservoir for externally administering drugs, attached to an outer support structure. Therefore, Lyer does not disclose a “first securing means for adhesively securing at least an end of the first vessel to the opening”, or a “second securing means for securing a portion of the second vessel to a corresponding portion of the outer surface of the body such that a hole formed in the portion of the second vessel is in fluid communication with the end of the first vessel”, as recited by claim 1 and claim 29.

Since Lyer fails to disclose each and every element of claims 1 and 29, from which all the other claims depend, the rejection of claim 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39 and 41-43 under 35 U.S.C. §102(e) is overcome and withdrawal thereof is respectfully requested.

The Examiner has also rejected claims 6 and 40 under 35 U.S.C. §103(a) as allegedly unpatentable over Lyer in view of U.S. Patent Publication No. 2002/0065545 to Leonhardt, et al. (hereafter “Leonhardt”). The rejection is respectfully traversed.

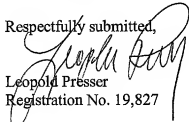
Applicants’ independent claims 1 and 29 are discussed above, from which claims 6 and 40 respectively depend.

Lyer is discussed above. Leonhardt discloses a graft, deployable percutaneously by low-profile deployment means and capable of providing a leak-proof conduit through the disease region without suturing or stapling. Leonhardt is relied on to teach a balloon catheter for urging inner members towards outer members. However, Leonhardt does not teach or suggest a

“first securing means for adhesively securing at least an end of the first vessel to the opening” and a “second securing means for securing a portion of the second vessel to a corresponding portion of the outer surface of the body such that a hole formed in the portion of the second vessel is in fluid communication with the end of the first vessel”. Thus, Leonhardt fails to overcome the underlying deficiencies of Lyer. Therefore, neither Lyer or Leonhardt, taken alone or in combination, discloses the combination of features recited in the Applicants’ independent claims. Nor is there any motivation in any of the references to combine such features. Accordingly, the rejection of claims 6 and 40 under 35 U.S.C. §103(a) based on the combination of Lyer and Leonhardt is overcome and withdrawal thereof is respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

  
Leopold Presser  
Registration No. 19,827

Scully, Scott, Murphy & Presser, P.C.  
400 Garden City Plaza, Suite 300  
Garden City, New York 11530  
(516) 742-4343  
FSD/HC:bk